

PX1. 0000 00 00 Photos of Contaminated 3T produced by Sorin Sorin-Baker_E00188245 et seq [ADD SWOBODA PHOTOS]**

PX2. 1980 00 00 Wendt et al Article: *Epidemiology of Infection by Tuberculous Mycobacteria* SORIN-BAKER_E00313168

PX3. 1983 00 00 Falkinham, Parker et al Article: *Epidemiology of Infection by Non-tuberculous Mycobacteria, Preferential Aerosolization of Mycobacterium Intracellulare from Natural Waters* SORIN-BAKER_E00313087

PX4. 1987 00 00 Exner et al Article: *Influence of Biofilms by Chemical Disinfectants and Mechanical Cleaning*, SORIN-BAKER_E00000963

PX5. 1988 00 00 JAMA Article Concentration of Mycobacterium avium by Hospital Hot Water Systems Peis 13

PX6. 2002 00 00 WEITKEMPER *HEATER COOLER UNIT—A CONCEIVABLE SOURCE OF INFECTION*, SORIN-BAKER_E00110887, PEIS KARST II EX. 88 P. 337 ET SEQ

PX7. 2002 et seq timeline [Sorin Misdeeds Van Schoor Rept Appdx G]

PX8. 2003 07 01 Falkinham Article: *Mycobacterial Aerosols and Respiratory Disease*, SORIN-BAKER_E00080616

PX 8B 2003 00 00 Montana State PPT re biofilm development Sorin-Karst 00034912, Falk 11/16/18 Ex 5

PX9. 2005 04 00 Heater – Cooler Competitive Matrix, SORIN-BAKER_E00009846

PX10. 2005 08 11 Production Hazard and Risk Analysis by Sorin and Lauda Sorin-Baker_E00009980, Peis 6/27/18 ex 4

PX11. 2009 08 00 FDA MDR Reports re Sorin 3T as of August 2009 from 2016 06 02 FDA-Presentation June-2-3 RE NTMS AND HCDS

PX12. 2010 08 00 Initial Sorin 3T IFU SORIN-BAKER_E00003888

PX 12B 2011 00 00 Prevention of Patient Exposure to RGM in Water Supply Sorin Karst 00034948

PX13. 2011 04 11 FDA LETTER TO SORIN RE FDA VISIT TO MUNICH PLANT SORIN-BAKER_E00048517, Dupoux 7/17/18 Ex 5-6, p. 59 – 83, PEIS KARST II, EX. 86, P. 284 ET SEQ

PX14. 2011 04 13 Dupoux Email to Peis et al SORIN-BAKER_E00219661

PX15. 2011 04 22 Email Dupoux and Peis attaching EPA Biofilm Article: *Control of Biofilm Growth in Drinking Water Distribution Systems*, SORIN-BAKER_E00254509 PEIS 6/27/18 KARST EX. 9 P. 64-6

PX16. 2011 06 17 Dupoux Email to Knott and Peis, Meeting Notes Dupoux Dep Ex 11

PX17. 2011 06 24 Email from Erwin Knott to Peis Dupoux attaching Study: *Heater/Cooler Disinfection—Rationale and Procedure*, SORIN-BAKER_E00154790, Dupoux 7/17/18 Exhibit 13, p. 123 - 143

PX18. 2011 07 08 Knott Email to Peis et al, SORIN-BAKER_E00154910, Monaghan Ex 12 Dep p. 223:2 – 225:22, Peis 6/27/18 dep Ex 15 p. 87 - 90

PX19. 2011 07 08 Email Peis to Frosel at Lauda SORIN-BAKER_E00154830

PX20. 2011 07 11 Dupoux Email to Peis SORIN-BAKER_E00142428, Dupoux 7/17/18 Exhibit 15, p. 145-57

PX21. 2011 07 11 Peis Letter to Dr. Grebner SORIN-PIEC_K00144232 SORIN-BAKER E00154914, Peis 6/27/18 dep Ex 58 p. 97: 8 - 99:13

PX22. 2011 07 28 Juhl Email to Peis attaching Weitkemper Peis Depo Exhibit 88, 89

PX23. 2011 07 28 Juhl Memo to Peis Risks of Contaminated Water coming into contact with blood SORIN-BAKER_E00220142 et seq Peis Depo Exhibit --

PX24. 2011 08 02 FDA Warning Letter SORIN-BAKER_E00014582, Light Dep Ex 20, Dupoux 7/17/18 Exhibit 17, p. 160-163

PX25. 2011 09 03 Dupoux Email to Peis et al Dep Ext 04 SORIN-KARST00252176

PX26. 2011 09 27 Risk Analysis Review at SORIN-BAKER_E00007683, Berch Ex. 13

PX27. 2012 05 23 Risk Analysis and Assessment SORIN-BAKER_E00006056

PX28. 2012 06 00 Updated Instructions for Water Cleanliness for Sorin 3T Davis Gerrald dep EX 8, GRN-Hosp_0000446, MONAGAHN EX. 4 AT P. 96-7

PX29. 2012 06 00 Sorin 3T IFU Vers 12 SORIN-BAKER_E00003690 at p. 44

PX30. 2012 06 12 TIMELINE OF ZURICH OUTBREAK, Table 1 Sax/Sommerst. Article

PX31. 2012 08 00 Email Feyerherm to Voorhees SORIN-BAKER E00114228

PX32. 2013 01 11 Email McKutcheon to Peis: *3T disinfection resistance & suggestions* SORIN-BAKER E00156238

PX33. 2013 01 13, Email Voorhees to Gordon Attached Updated Instructions SORIN-BAKER E00114150

PX34. 2013 02 00, email dated 2014 02 06 from Dr. Sax to Sorin SORIN-MDL00015507

PX35. 2013 03 00 excerpt Somerstein USZ Outbreak Article SORIN-PIEC K00017563 SORIN-BAKER E00046079

PX36. 2013 03 21 Acherman et al Article: *Prosthetic Valve Endocarditis and Bloodstream Infection Do to Mycobacterium Chimaera*

PX37. 2013 09 00 GHS Sorin 3T Heater/Cooler Cleaning Log 2013 Davis Gerrald dep ex 12 Grn-Hosp_00000122

PX38. 2013 09 00 EMAIL DATED 2014 04 14 FROM PEIS TO FRESE RE COMMUNICATIONS WITH DR SAX IN SEPT 2013 SORIN-MDL00015403 Dupoux 7/17/18 Ex. 23 p. 226 et seq; KHORRAN dep p. 93 -5

PX39. 2013 10 00, EMAIL DATED 2014 06 14 FROM PEIS TO SWISSMEDIC ENCLOSING RESPONSES TO SWISSMEDIC AT SORIN-MDL0002498

PX40. 2013 10 01 et seq GHS Chart Main Water Feed pos tests susp M. Abscessus pltf_f_johnson00000033_

PX41. 2013 11 00 Surgery in Hawaii with 3T 2013 infxn 4 yrs later in 2017 SORIN-MDL00013067

PX42. 2013 11 08 Email Peis to Kohler SORIN-MDL00015390

PX43. 2014 01 30 Swiss Medic Alert from Zurich Hospital PA 000952.pdf, Peis 6/27/18 Page 106- 9 : Exhibit 23

PX44. 2014 01 30 Swiss medic report SORIN-PIEC K00017563 [original german]

PX45. 2014 02 06 Email from Sorin to Sax SORIN-MDL00015507 (dupl of Ex. 28)

PX46. 2014 02 07 email christine dees to e stefani re zurich sorin-baker_e00046115

PX47. 2014 02 14 Sorin Medwatch Form FDA Sorin Baker # 00037732

PX48. 2014 03 14 Somerstein Zurich Investigation Results: *Evaluation of a Cluster of Mycobacterium chimera Infections in Cardiac Surgery Patients Zürich University Hospital* SORIN-PIEC K00017560, Dupoux 7/17/18 Ex. 21 p. 216 - 223

PX49. 2014 04 10 Email Dr. Sax to Peis Hofstetter dep ex 23

PX50. 2014 04 12 Email from Waldman SORIN-PIEC_KOO 146853 SORIN-BAKER_E00157535, Schmidt 2018 02 08 Ex. 3

- PX51. 2014 04 14 FROM PEIS TO FRESE RE COMMUNICATIONS WITH DR SAX IN SEPT 2013 SORIN-MDL00015403 Dupl. of Ex. above, Dupoux 7/17/18 Ex. 23 p. 226 et seq; KHORRAN dep p. 93 -5
- PX52. 2014 04 28 and 04 10 Dupoux Depo Ex 23 Email Dr Sax to Dupoux
- PX53. 2014 05 16 Emails between Zurich Dr. Sax and Peis with Meeting Summary SORIN-MDL00015413, Richter Dep Exhibit
- PX54. 2014 06 26 Int Email at CDC, William Kelly EX 13 Sorin-SC00001336
- PX55. 2014 06 27 GHS initial letter to patients
- PX56. 2014 06 30 Swissnos notice: *Possible exposure of heart surgery patients to non-tuberculous mycobacteria* Dupoux Depo Ex 24, p. 239 - 246
- PX57. 2014 07 00 GHS Media Statement, from DHEC binder Cox Dep Ex 1.
- PX58. 2014 07 01 Basel Switz has MC in its 3Ts SORIN-BAKER_E00255516, Peis 6/27/18 dep ex. 27 p. 118 – 120, Dupoux Depo Ex 25, p. 239 - 246
- PX59. 2014 07 02 Swiss Medic Document not just a local problem SORIN-BAKER_E00046050
- PX60. 2014 07 03 Email Knott to Peis SORIN-BAKER_E00221205 Monaghan Ex. 14.p. 230-18, Peis 6/27/18 at ex. 29 p. 125 -7, new disinfxn method, Dupoux 7/17 18 Exhibit 26, p. 247 et seq it wont work
- PX61. 2014 07 03 Draft 3 of Impt Info Letter Frese to Sorin SORIN-BAKER_E00221189
- PX62. 2014 07 08 Dupoux Email to Peis we don't know what bug we want to kill SORIN-BAKER_E00255519, Dupoux Ex. 27, Peis Ex. 30
- PX63. 2014 07 09 Email Dupoux Peis Sorin-Baker_E00255520
- PX64. 2014 07 09 Email from Peis Biofilm cannot be killed by current cleaning regime PIEC, Peis Dep. Ex.
- PX65. 2014 07 10 Email Chain Shanna and Ratzlaff 3 months recommended SORIN-BAKER_E00056676
- PX66. 2014 07 10 Email Frese to Swiss Medic with Talbot Results SORIN-BAKER_E00027238
- PX67. 2014 07 10 Talbot Emails with Peis Re FAQs for Sales force SORIN-BAKER_E00157239, Talbot Ex. 08, 09 p. 135:1 – 155:25, PEIS KARST II EX. 31 AND 32, AND RICHTER EX 3A, P. 384-6, etc.
- PX68. 2014 07 11 Frese to Koch email re press release Peis Depo Exhibit 33
- PX69. 2014 07 14 Sorin Cover Letter [E00046007] Attaching Email [E0050708] and Dear Valued Customer Letter [to customers in Europe] SORIN-BAKER_E00000480 – 85. Monaghan Ex 11 Dep p.; PEIS 6/27/18 EX. 34 P. 147 – 150m /Dupoux ex 31 p. 283 - 5
- PX70. 2014 07 14 SWISS MEDIC PRESS RELEASE GOES OUT UNCHANGED SORIN-BAKER_E00046041 PEIS KARST EX. 33A
- PX71. 2014 07 16 Katja Richter Meeting Minutes Sorin and Zurich Hospital SORIN-BAKER_E00359375 Richter Dep Exhibit 01
- PX72. 2014 07 16 Meeting Minutes Hoffmann Email where whole genome seq recommended not RAPD PCR SORIN-BAKER_E00157398, Talbot Ex. 6 p. 113:10 – 114:6
- PX73. 2014 07 17 Katja Richter Meeting Minutes Basel Based on NDA Erich Offered 1 week 6 Sigma Richter Dep Exhibit 01
- PX74. 2014 07 18 GHS Update Letter to Clients

PX75. 2014 07 22 Email from Triemli Hosp to Sorin their 3Ts are contaminated with MC SORIN-BAKER_E00158167, Peis Ex. 4, 90

PX76. 2014 07 23 Katja Richter to Many with FAQs SORIN-BAKER_E00050751, Talbot Ex. 08, 09

PX77. 2014 07 23 Demonstrative Exhibit Showing Differences between the FAQ versions

PX78. 2014 07 23 Email Shanna to Mattson I had a bad feeling this was going to happen SORIN-BAKER_E00063495 Mattson Ex. 3

PX79. 2014 07 23 Email from Hofstetter to Trevor Basel Zurich and Sion 3Ts new ones bc there is bact in old ones SORIN-MDL00029839 Trevor Ex 10

PX80. 2014 07 25 Email Shanna to Sean I wasnt able to share as much as I wanted SORIN-BAKER_E00050756, Schmidt Ex. 11 p. 80

PX81. 2014 07 29 Email Shanna Schmidt SORIN-BAKER_E00063504

PX82. PX 0082 2014 08 00 Sorin Response to GHS Medwatch SORIN-BAKER_E00048647

PX83. 2014 08 01 Khorran Letter from Sorin to all US hospitals GRN-HOSP_00000462, Monaghan Ex 9 Dep p. 150-55, PEIS 6/27/18 EX 38 P. 161-171, Dupoux 6/27/18 Exhibit 31 p. 283 - 285

PX84. 2014 08 01 Demonstrative Exhibit Comparison Table of the 3 Letters

PX85. 2014 08 01 GHS files MDR with FDA says common denominator is Sorin 3T SORIN-BAKER_E00201904

PX86. 2014 08 13 Email Chain Sorin Salesmen no communication is the ultimate careful communication SORIN-BAKER_E00326911, Schmidt Ex. 12

PX87. 2014 09 02 Dupoux Peis emails Lauda line is positive Peis Depo Exhibit 95, PEIS KARST II P. 394 -5

PX88. 2014 09 04 Peis Memo to Grebner

PX89. 2014 09 05 Email Galasso to Peis Dupoux et al Peis Depo Exhibit 96

PX90. 2014 09 08 Peis email Dupoux Depo Ex 30 Biofilm found in 3Ts in plant on 9/4, p. 276 - 283

PX91. 2014 09 26 *Disinfection strategies of Heater/Cooler devices by Lauda* Dupoux Depo Exhibit 37 Dupoux analysis of Lauda Issues incl biofilm

PX92. 2014 09 26 Email Ebner to Peis PA004707 K00171891 , Mattson Ex. 15

PX 092B 2014 09 29 Frese to Peis email Biofilm HC letter SORIN-BAKER_E00157860 Peis Karst II Ex 93 p. 387 - 90

PX93. 2014 10 00 Summary Report Obvious that H2O2 has shown no mycobacterial impact SORIN-BAKER_E00026878

PX94. 2014 10 01 Hoffstetter email to Sorin Group with FAQs, Dupoux Ex 36 p. 26 - 32

PX95. 2014 10 06 SwissMedic email to Peis PEIS Depo Exhibit 06

PX96. 2014 10 14 AEROSOL RELEASE REPORT 3T SORIN-BAKER_E00211764 Sorin.Baker 37211.37218, Dupoux 7/17/18 Exhibit 33, p. 298 - 302

PX97. 2014 10 16 Dupoux Depo Exhibit 33 Aerosol Release Report signed Peis

PX 97B 2014 10 17 Root Cause Investigation SORIN-BAKER_E00026106 Peis Karst I Ex 48 tests perfd on new HC devices after tstng prodn line show freq pos rslts for MC.pdf, p. 199 et seq

PX98. 2014 10 20 Root Cause Investigation Summary Report SORIN-BAKER_E00047461 Monaghan Ex. 16, Peis Karst 2 Peis Ex. 51 at p. 195 et seq

PX99. 2014 10 28 CAPA MYCO FOUND IN NEW SORIN 3TS Peis Depo Exhibit 49

PX100. 2014 11 04 Complaint Investgn Rpt re biofilm Dupoux Depo Exhibit 40

PX101. 2014 11 07 Peis emails with Prof Werner re use 3T in the OR Dupoux Depo Exhibit 38, p. 347 et seq, PEIS Ex. 51

PX102. 2014 11 07 Peis letter to FDA Dupoux Depo Ex 39, PEIS EX. 54 P. 215 ET SEQ

PX103. 2014 11 13 Email Essen Hosp to Sorin general problem which current disinxn regimen is obv unable to eliminate SORIN-BAKER_E00163176

PX104. 2014 12 01 Galasso to Oelgarth Hospitals want 3T out of OR SORIN-BAKER_E00158225

PX105. 2014 12 04 Email from Waldman SORIN-PIEC_KOO 146853 SORIN-BAKER_E00157535

PX106. 2014 12 23 Letter Khorran to FDA Peis Ex 15

PX107. 2014 GHS Isolate Testing 95% similar

PX108. 2015 01 05 EMAIL Peis to FDA SORIN-BAKER_E00032893 FDA asks why are there two letters July 14 and Aug 1, Peis Karst II Ex. 57 p. 221 et seq

PX109. 2015 03 25 Email Dupoux to Peis with timeline Peis dep ex 23, Dupoux 7/1818 Ex. 42, p. 394 et seq

PX110. 2015 04 20 Sorin Field Action Plan Peis dep ex 34

PX111. 2015 04 27 Root Cause Investigation Summary Report SORIN-BAKER_E00026108, dupoux 7/18/18 Ex. 44 p. 433 et seq. Peis Karst II Ex. 61 p. 226 et seq

PX112. 2015 05 14 Email Chain Peis Dupoux Peis is burned out SORIN-BAKER_E00147658 Dupoux 7 18 18 Ex 45 p. 445 et seq

PX113. 2015 05 15 Sorin Risk Review SORIN-BAKER E00038547

PX114. 2015 05 28 Letter Katja Richter Peis dep ex 27 loaner units

PX115. 2015 05 29 Summary of NTM complaints and corrective action Dupoux Depo Ex 34

PX116. 2015 06 01 IFU SORIN-BAKER_E00030324 NB P 24 1st time says point 3T away from op table

PX117. 2015 06 03 FSN from Ds to Foreign Hospitals SORIN-BAKER_E00022006, Dupoux Ex, Peis Ex. Khorran Ex.

PX118. 2015 06 05 Khorran Letter to FDA SORIN-BAKER_E00001645, Dupoux 7/1818 Ex. 46 p. 461 et seq

PX119. 2015 06 10 Email Katja Richter Sorin-Baker_E00135082 "*We need to be careful*" Richter Ex. 20

PX120. 2015 06 10 Disnfxn Decontam proposal nb p. 27 assumes "90% of units in Europe are contaminated, Hoffstetter Ex. 35

PX121. 2015 06 15 Class 2 Device Recall STOCKERT HEATERCOOLER SYSTEM 3T

PX122. 2015 06 15 Dupoux Depo Exhibit 62 Dupoux on Design changes must be done to fix aerosols

PX123. 2015 06 15 FSN FIELD SAFETY NOTICE Sorin- Baker_E00032828 Sorin's investigation of aerosol release confirmed Dr. Sax's hypothesis that 3Ts could release mycobacteria into the air, was not provided to U.S. hospitals until June 15,2015, WOOD, EX. 13

PX124. 2015 06 15 Email Jeff Riley at Mayo Clinic to Sorin attaching Sax/Somm and asking when did Sorin Know about this article SORIN-BAKER_E00052143

PX125. 2015 06 15 DVC Lttr 3t SORIN-BAKER_E00000486, Monaghan Ex 23 p. 256:2 – 259:14

PX126. 2015 06 16 Email Chain "water is the big mystery" SORIN-BAKER_E00056977

PX127. 2015 06 19 Schmidt to Team sell 3Ts with HLMs SORIN-BAKER_E00059377, Schmidt Ex. 19

PX128. 2015 06 22 Shanna Schmidt emails Sorin-Baker_E00057178 "*Munich is prioritizing*", Monaghan Ex. 39 p. 345:9 – 348: 18

PX129. 2015 07 00 Sax Somerstein Article

PX130. 2015 07 00 Sax Somerstein Article Suppl Data

PX131. 2015 07 02 Email Dupoux to Olgarth Dupoux Depo Ex 48, P. 473 et seq

PX131B DUPLICATE OF PX 138 2015 09 07 EMAIL WALDMANN TO PEIS re "*FORESEEABLE*" Dupoux Depo Ex 47

PX132. 2015 07 13 Sorin summarizes the 3T issues Sorin Baker # 00020006

PX133. 2015 08 06 FSN 3T is source of contamination Sorin Baker 000499882

PX134. 2015 08 12 kreul ex 1 email

PX135. 2015 08 27 FDA inspn citation and Form 483 SORIN-BAKER_E00030867, Peis Karst II p. 248-252 Ex. 70

PX136. 2015 08 27 Shanna Schmidt Email "*Are we even going to have a suitable disinfectn pgrm?*" SORI N-BAKER E00058599, Schmidt Ex. 32 at p. 123

PX137. 2015 09 04 Monaghan Memo re Conf Call Sales and 3T Mgr discrepancies conflicting info and source of truth Monaghan 34, p. 313:10 – 315:11

PX138. 2015 09 07 EMAIL WALDMANN TO PEIS re "*FORESEEABLE*" Dupoux Depo Ex 47 [THIS DOCUMENT IS ACTUALLY DATED JULY 9]

PX139. 2015 09 12 Dupoux Email Dep Ex 50 Sorin-Baker 324734- 324736 "*industry issue*" dupoux 7/18/18 p. 481 et seq

PX140. 2015 09 18 Sorin response to FDA form 483 Dupoux Depo Exhibit 51

PX141. 2015 09 23 Sorin Risk Review re Laud Peis dep ex 17

PX142. 2015 10 00 DVC Letter from Sorin Sorin-Baker_E00049442, Monaghan Ex. 25 p. 278:10 – 281:2, Dupoux 7/18/18 Ex 52 p3 p. 511 et seq; Peis Karst II Ex. 72 p. 252 et seq.

PX143. 2015 10 15 FDA Safety Communications > Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices/ FDA Safety Communication

PX144. 2015 10 20 Email Katja Richter to Wood Pos Test after Disinfxn SORIN-BAKER E00138417 Wood 17

PX145. 2015 10 29 Email Prof Falk. to CDC Falkinham dep ex 39

PX146. 2015 11 12 Meeting Recap FDA and LivaNova SORIN-BAKER_E00015442 "*machines infected with biofilm cannot be decontaminated by the disinfection procedure in the IFU.*"

PX147. 2015 11 18 Email Peis to Dupoux Dupoux Depo Ex 56 "*strains from the Lauda production and HC3T devices in the field are either identical (four strains are identical) or show small deviation in the genome.*", Talbot Ex. 07 p. 126 - 135

PX148. 2015 12 02 Berch 06 focus on sealing the tank Alt Design possible

PX149. 2015 12 02 Sorin FAQs SORIN-BAKER_E00051901 Monaghan 35

PX150. 2015 12 04 Schmidt to others 75 3Ts waiting for adoption 30 days before FDA stops sales SORIN-BAKER...E00051899 Monaghan 40, p. 348: 15 – 350:2

PX151. 2015 12 09 Email Niemann to Peis Dupoux Depo Exhibit 57 "*inarguable proof of an outbreak*", most likely from your production line."

PX152. 2015 12 09 Berch 07 NTMs can go from 3 Mt to 3Km

PX153. 2015 12 10 Dupoux Depo Exhibit 55 Dupoux QA sumry deep clean not enough and rapid degradation of 3T

PX154. 2015 12 14 WOOD TO Peis Several 3Ts had deep disinfxn then got pos NTM test SORIN-BAKER_E00285394 Coyle Exhibit 27

PX155. 2015 12 15 Berch 09 Engr Rpt on 3T Fan and getting rid of it

PX156. 2015 12 29 FDA warning letter to Sorin 3T may be refused admission adulterated SORIN-BAKER E00020441, Dupoux 7/18/18 Ex. 59 is the response, p. 534 et seq.

PX157. 2015 cambridge Abscessus infection 3T

PX158. 2015 Prodn Hazard Analysis SORIN-BAKER_E00230904

PX159. 2015 Sax Article Where it all began SORIN-BAKER_E00045804

PX160. 2016 00 00 Sorin Doc probs w biofilm growth in areas not contacting H2o SORIN-BAKER_E00099573

PX161. 2016 00 00 Garvey Article Decontamination of heater-cooler units associated with contamination by atypical mycobacteria Peis dep ex 19

PX162. 2016 01 00 Sorin DVC Letter re FDA Warning Ltr Sorin Baker 0051220 Monaghan 26, Monaghan Ex. 25 p. 278:10 – 281:2

PX163. 2016 01 05 Sorin Press release re FDA letter SORI N-BAKER EO0205743

PX164. 2016 01 12 Berch 11 Sorin 3T remediation plan acknowledges Problems

PX165. 2016 01 12 Sorin letter to FDA strict adherence is successful SORIN-BAKER_E00000799 Dupoux 7/18/18 Ex 59 p. 535 et seq

PX166. 2016 01 20 Coyle 17 Sorin Response to FDA questions

PX167. 2016 01 29 Email Dupoux to Peis and Falkinham Memo SORIN-BAKER_E00197838

PX168. 2016 02 01 EMAIL JOE FALK TO SORIN H202 MAY INCR NTM GROWTH IN BIOFILM OOPS SORIN-BAKER_E00191947; Dupoux 7/18/18 Exhibit 60 p. 543 et seq

PX169. 2016 02 02 SORIN-BAKER_E00196573 Peis says H2o2 wont work

PX170. 2016 02 04 Email Dupoux to Falk UNDERSIDE OF HCD LIDS ARE CONTAM'D SORIN-BAKER_E00197829 Dupoux 7/18/18 Exhibit 61 p. 546 et seq

PX171. 2016 02 04 Falkinham Resp to Dupoux SORI N-BAKER_EOO 191944, Falkinham Ex. 12 p. 80

PX172. 2016 02 04 EMAIL Prof Falk to Dupoux re H202

PX173. 2016 02 08 Prof Falk to Dupoux Falkinham dep ex 14 Hot water can kill NTMs

PX174. 2016 02 08 Email Dupoux to Prof Falk Falkinham dep ex 17 re Hot water

PX175. 2016 02 08 Email Dupoux to Prof Falk Falk dep ex 16 re hot water

PX176. 2016 02 08 Prof Falk to Dupoux Falkinham dep ex 15 Hot water can kill NTMs

PX177. 2016 02 11 Email Berch Ex. 13 to Sorin Design *won't allow cover to be disinfected* SORIN-BAKER_E00170773

PX178. 2016 03 03 3T Coyle 21 complaint retrospective review re whether Sorin met FDA regs

PX179. 2016 03 07 FDA letter to Sorin big probs INCL NO VALIDATION OF CLEANING SORIN-BAKER E00016648, Peis Karst Ex. 76, p. 260 et seq

PX180. 2016 03 17 SORIN-BAKER E00027243

PX181. 2016 03 22 Berch Ex. 17 Sorin testing 3T aerosol emission with videos and smoke pens

PX182. 2016 03 23 Haller Study from Germany Point Source for German infections SORIN-BAKER_E00093268, Peis Ex. 22

PX183. 2016 03 29 EMAIL NIEMANN TO PIES SORIN 3T SAMPLES IDENTICAL TO PATIENT ISOLATES SORIN-BAKER_E00241157, Olin Ex. 20

PX184. 2016 04 06 Sorin email to Prof Falk. Falkinham dep ex 21

PX185. 2016 04 07 Berch 23 long memo with charts graphs preventing NTM emission 3T

PX186. 2016 04 08 Email Peis to Dupoux et al Peis dep ex 21

PX187. 2016 04 09 Berch 20 Berch email about aerosol release tests and 3T

PX188. 2016 04 16 Sorin Engineering Report re Aerosolization SORIN-BAKER_E00033973, Peis Ex., Dupoux Ex., Olin Ex.

PX189. 2016 04 20 Falkinham PPT Falkinham dep ex 19

PX190. 2016 05 02 Email chain Falkinham Peis SORIN-PIEC_KOO 185854

PX191. 2016 05 02 Email Wood to FDA SORIN-BAKER_E00031470 1st notification of genetic matches by Sorin to FDA, Wood Ex. 22

PX192. 2016 05 09 Sorin Admission of Aerosol Emission nb p. 18 SORIN-BAKER_E00042562

PX193. 2016 05 13 Berch 13 discussion of endoscopes and tank turbulence

PX194. 2016 05 16 NTM INFECTIONS AND HCU WEBINAR FDA

PX195. 2016 05 31 Prof Waldman from Sorin Statistical estimation of infection risk SORIN-BAKER_E00192267, PEIS EX. 79 P. 270 ET SEQ

PX196. 2016 05 31 Email Falk. to Zambotto Falkinham ex 23

PX197. 2016 06 01 excerpt from School mag

PX198. 2016 06 01 VIDEO Sommerstein-testing HCUs air movement, smoke= transmission of MC

PX199. 2016 06 01 Email Dupoux to FDA asking FDA to not issue safety alert SORIN-BAKER_E00257254, Dupoux Ex.

PX200. 2016 06 01 Email Prof Falk to Sorin with Photo Falkinham dep ex 24

PX201. 2016 06 01 FDA Safety Communications > Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stöckert 3T Heater-Cooler System/ FDA Safety Communication

PX202. 2016 06 01 Sommerstein-testing HCUs air movement, smoke=Transmission of Mycobacterium chim

PX203. 2016 06 02 Dupoux 02 Sorin Presentation to Circulatory Devices Panel, Dupoux Ex., p.

PX204. 2016 06 02 FDA-Presentation June-2-3 RE NTMS AND HCDS. Dupoux Ex., p

PX205. 2016 06 02 NTMs in HCDs in PA Article Dupoux 2 Ex. 19

PX206. 2016 06 02 Dupoux 03 Transcript of FDA Hearing with Test from Dr. Sax Dupoux Falkinham et al

PX207. 2016 06 03 Transcript of Day 2 FDA Panel on HCUs and NTM infxns

PX208. 2016 06 13 Biofilm will develop over time SORIN-BAKER_E00049563, Dupoux Prescott 11/30/17 Exhibit 11 p. 180 et seq

PX209. 2016 06 15 Dupoux Email to Lauda re recalls SORIN-BAKER_E00260084 Dupoux 7/18/18 Exhibit 62 p. 558 et seq

PX210. 2016 06 16 Schmidt email to Voorhees Water is the big mystery owe our clients better explanations SORIN-BAKER_E00056977

PX211. 2016 06 21 Berch 22 Bacterial growth graph in Sorin 3T

PX212. 2016 07 01 Abscessus after 3T operation PA
 PX213. 2016 07 02 Dupoux 2 Ex. 04 Swiss Medic doc
 PX214. 2016 07 04 Berch 19 Aerosolization tests failed
 PX215. 2016 07 30 Berch 26 Dupoux email admits aerosols and trying to fix issue
 PX216. 2016 08 07 Berch email to Team finalize upgrade to Seal 3T SORIN-BAKER_E00182954 Berch Ex 26A
 PX217. 2016 09 08 Myc Chelonae found in Essen 3T
 PX218. 2016 09 08 NTM infections in 3ts SORIN_BAKER_E00333950_native NTM Report
 PX219. 2016 09 08 SORIN-BAKER_E00333950 CHELONAE FOUND IN ESSEN
 PX220. 2016 10 00 Sorin FAQs Sorin Baker 00020261 Monaghan 29 p. 285:8 – 289:8
 PX221. 2016 10 00 SORIN-BAKER_E00044212 SORIN CORRECTIVE ACTION PLAN
 PX222. 2016 10 05 Falkinham dep ex 30 SORIN-KARST00229837
 PX223. 2016 10 13 FDA Safety Communications > UPDATE/ Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System/ FDA Safety Communication
 PX224. 2016 10 14 NOTES FROM THE FIELD RESULTS STRONGLY SUGGEST POINT SOURCE CONTAMINATION, Talbot Ex. 5
 PX225. 2016 10 15 Dupoux Depo Exhibit 63 Dupoux Action plan overview FDA action resonates with me
 PX226. 2016 11 11 Salfinger email to Peis SORIN-BAKER_E00044778 Zurich got pos tests every few months
 PX227. 2016 11 27 Sorin Admits Aeresols SORIN-BAKER_E00338782, Talbot Ex. 11, p. 177 -189
 PX228. 2016 12 12 Dupoux Depo Exhibit 66 Risk Mitgn take 3T out of the OR
 PX229. 2016 12 16 Letter CDC to SC Patient re 3T
 PX230. 2017 00 00 ALLEN ARTICLE
 PX231. 2017 00 00 Lyman Art airborne transmn via aerosolization SORIN-BAKER_E00309628
 PX232. 2017 02 16 Email Chain among Sorin Employees incl. “*he is clueless*” SORIN-BAKER_E00184054, MONAGHAN ex. 38 p. 341: 6 – 345:6
 PX233. 2017 04 12 SORIN-BAKER_E00044316 LETTER EXPLAINING CHANGES MADE TO 3T
 PX234. 2017 05 00 Inge Article SORIN-BAKER_E00309628
 PX235. 2017 07 12 Van Ingen Article Peis dep ex 22
 PX236. 2017 08 17 Sorin Press Release re new design 3T Dupoux dep ex 4
 PX237. 2017 11 30 Dupoux says in depn if there is water contamn is inevitable and scrubbing required
 PX238. 2018 03 00 SOMMERSTEIN Global Health Estimate of Invasive Mycobacterium chimaera Infections Associated with Heater–Cooler D
 PX239. 2019 06 00 Talbot plan to change Tubing 3T SORI N-BAKER_E00021716 Talbot 15, p. 205 - 211
 PX240. 2019 06 27 Ds Patent Application for Vacuum Sealed 3T
 PX241. 2019 09 04 Chelonae found in another Sorin 3T
 PX242. 2022 08 23 Amended and Revised Fact Sheet _Redacted
 PX243. 2022 10 23 DIAGRAM OF HCD

PX 300 2019 10 04 Expert Report of Dr. William Jarvis with all exhibits and references

PX 301 2020 07 01 Jarvis Rebuttal Report with all exhibits and references

PX 302 2019 10 06 Swoboda Report Final with all exhibits and references

PX 303 2019 10 08 Chad Roy Report with all exhibits and references

PX 304 2020 06 29 Roy Rebuttal Report with all exhibits and references

PX 305 2019 10 07 Laux Report with all exhibits and references

PX 306 Laura Lampton expert reports with all exhibits and references

PX 307 2023 05 05 Expert Report of Glen Adams

PX 308 Expert Reports of Dr. Oliver Wood

